

JUN 22 2004

PTO/SB/08A (08-03)  
Approved for use through 07/31/2006. OMB 0851-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/805,843       |
| Filing Date            | March 22, 2004   |
| First Named Inventor   | GONZALO ROMERO M |
| Art Unit               | 1654             |
| Examiner Name          |                  |
| Attorney Docket Number | ROMERO           |

|       |   |    |   |
|-------|---|----|---|
| Sheet | 1 | of | 1 |
|-------|---|----|---|

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS |          |                                              |                                |                                                 |                                                                           |                |
|--------------------------|----------|----------------------------------------------|--------------------------------|-------------------------------------------------|---------------------------------------------------------------------------|----------------|
| Examiner Initials*       | Cite No. | Foreign Patent Document                      | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | P <sup>o</sup> |
|                          |          | Country Code* Number * Kind Code* (if known) |                                |                                                 |                                                                           |                |
| SN                       | 7        | JP 09249579                                  | 09-22-1997                     | HIROSHI                                         | p.1 abstract                                                              | ✓              |
| SN                       | 8        | JP 10120593                                  | 05-12-1998                     | MASARU                                          | p.1 abstract                                                              | ✓              |
| SN                       | 9        | WO 9921542 A 2                               | 05-06-1999                     | MCGRATH                                         | p.1,8,25,28-30.                                                           |                |
| SN                       | 10       | WO 0203879 A 1                               | 01-17-2002                     | GROTH                                           | p.4, p.6.                                                                 |                |
|                          | 11       | WO 02067066                                  | 09-06-2002                     | MORRE                                           | p.1 abstract                                                              |                |

**Examiner  
Signature**

Stollman

Date  
Considered

4-25-07

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|                                                                                                                                       |      |                          |                  |
|---------------------------------------------------------------------------------------------------------------------------------------|------|--------------------------|------------------|
| Substitute for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |      | <b>Complete if Known</b> |                  |
|                                                                                                                                       |      | Application Number       | 10/805,843       |
|                                                                                                                                       |      | Filing Date              | March 22, 2004   |
|                                                                                                                                       |      | First Named Inventor     | GONZALO ROMERO M |
|                                                                                                                                       |      | Art Unit                 | 1654             |
|                                                                                                                                       |      | Examiner Name            |                  |
| Sheet 1                                                                                                                               | of 8 | Attorney Docket Number   | ROMERO           |

| NON PATENT LITERATURE DOCUMENTS |                       |                                                                                                                                                                                                                                                                             |                |
|---------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.             | T <sup>2</sup> |
|                                 | 12                    | ANDREWS, J. The domesticated capsicum. 1984. University of Texas press. Austin.                                                                                                                                                                                             |                |
| SH                              | 13                    | BAR-SHAVIT Z, GOLMAND R, STABINSKY Y, GOTTLIEB P, FRIDKIN M, TEICHBERG V.I, BLUMBERG S. Enhancement of phagocytosis-a newly found activity of substance P residing in its n-terminal tetrapeptide sequence. Biochem and Biophy Research Comm. 1980. Vol. 94, pp. 1445-1451. |                |
| SH                              | 14                    | BELITZ H.D, GROSCH W. Food chemistry. 1987. Springer-verlag. Berlin-                                                                                                                                                                                                        |                |
|                                 | 15                    | BERNSTEIN J.E. Capsaicin in the treatment of dermatologic disease. Cutis. 1987. Vol 39, pp. 352-353.                                                                                                                                                                        |                |
| SH                              | 16                    | BERNSTEIN J.E, BICKERS D.R, DAHL M.V, ROSHAL J.Y. Treatment of chronic postherpetic neuralgia with topical capsaicin. Journal of American Academy Dermatology. 1987. Vol 17, pp. 93-96.                                                                                     |                |
|                                 | 17                    | BLACK J.G. Microbiology. Principles and applications. 1993. Marymount University. Prentice Hall, New Jersey.                                                                                                                                                                |                |
| SH                              | 18                    | BLATTEIS C.M. Physiology and pathophysiology of the temperature regulation. 1998. University of Tennessee, Memphis. World Scientific Publishing.                                                                                                                            |                |
|                                 | 19                    | BUCK S.H, BURKS T.F. Neuropharmacology of capsaicin: review of some recent observations. Pharmacological Reviews. 1986. Vol 38, pp. 179-272.                                                                                                                                |                |
| SH                              | 20                    | CHAHN L.A, LYNCH A.M. The acute effects of capsaicin on the cardiovascular system. Acta Physiologica Hungarica. 1987. Vol 69, pp. 413-419.                                                                                                                                  |                |

|                    |          |                 |         |
|--------------------|----------|-----------------|---------|
| Examiner Signature | Stoffman | Date Considered | 4-28-07 |
|--------------------|----------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/805,843       |
| Filing Date            | March 22, 2004   |
| First Named Inventor   | GONZALO ROMERO M |
| Art Unit               | 1654             |
| Examiner Name          |                  |
| Attorney Docket Number | ROMERO           |

Sheet

2

of

8

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| GH                 | 21                    | CHEMICAL INDUSTRY. Report developmental toxicology of polyoxyethylene sorbitan monooleate (cas# 9005-65-6) in sprague-dawley cd rats, abstract. 1992 Internet.                                                                                                  |                |
| SH                 | 22                    | CICHEWICZ R.H, THORPE P.A. The antimicrobial properties of chile peppers (capsicum species) and their uses in Mayan medicine. J of Ethnopharmacology. 1996. Vol 52, pp. 61-70.                                                                                  |                |
|                    | 23                    | GROMBIE L, DANDEGAONKER S.H, SIMPSON K.B. Amides of vegetable origin. Part VI. Synthesis of capsaicin. J of the Chemical Society. 1955. pp. 1025-1027. London.                                                                                                  |                |
| GH                 | 24                    | DEWITT D. The chile pepper encyclopedia. 1999. William Morrow and Co, Inc. New York.                                                                                                                                                                            |                |
|                    | 25                    | DEWITT D, STOCK M.T, HUNTER K. The healing powers of peppers. 1998 Three Rivers Press, New York.                                                                                                                                                                |                |
| GH                 | 26                    | EGLEZOS A, ANDREWS P.V, BOYD R.L, HELME R.D. Review modulation of the immune response by tachykinins. Immunology and Cell Biology. 1991. Vol 69, pp. 285-294.                                                                                                   |                |
| SH                 | 27                    | FRAENKEL-CONRAT H, KIMBAL P.C. Virology. 1982. Prentice-Hall, Inc, Englewood Cliffs, N.J.                                                                                                                                                                       |                |
| SH                 | 28                    | FRANCO R, COSTA M, FURNESS J.B. Evidence that axons containing substance P in the guinea-pig ileum are of intrinsic origin. Naunyn-Schmied Arch of Phar. 1979. Vol 307, pp 57-63.                                                                               |                |
|                    | 29                    | GANNETT P.M, IVERSEN P, LAWSON T. The mechanism of inhibition of cytochrome P45011E1 by dihydrocapsaicin. Bio-organic Chemistry. 1990. Vol 18, pp. 185-198.                                                                                                     |                |
| GH                 | 30                    | GILMAN S.C, SCHWARTZ J.M, MILNER R.J, BLOOM F.E, FELDMAN J.D. B-endorphin enhances lymphocytes proliferative responses. Proceed of Nat Acad of Sciences. 1982. Vol 79, pp. 4226-4230.                                                                           |                |

Examiner  
Signature

Stoffman

Date

Considered

4-25-07

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|                                                                                                          |             |                          |                  |
|----------------------------------------------------------------------------------------------------------|-------------|--------------------------|------------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |             | <b>Complete if Known</b> |                  |
|                                                                                                          |             | Application Number       | 10/805,843       |
|                                                                                                          |             | Filing Date              | March 22, 2004   |
|                                                                                                          |             | First Named Inventor     | GONZALO ROMERO M |
|                                                                                                          |             | Art Unit                 | 1654             |
| Examiner Name                                                                                            |             |                          |                  |
| Sheet <b>3</b>                                                                                           | of <b>8</b> | Attorney Docket Number   | ROMERO           |

| NON PATENT LITERATURE DOCUMENTS |                       |                                                                                                                                                                                                                                                                 |                |
|---------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| GAH                             | 31                    | GLINSUKON T,STITMUNNAITHUM V,TOSKULKAO C,BURANAWUTI T,TANGKRISANAVINONT V.Acute toxicity of capsaicin in several animal species.Toxicol.1980.Vol 18,pp. 215-220.                                                                                                |                |
|                                 | 32                    | HARBOUR D.A,HILL T.J,BLYTH W.A.Recurrent herpes simplex in the mouse.inflammation in the skin and activation of virus in the ganglia following peripheral stimulation.Journal of General Virology.1983.Vol 64,pp. 1491-1498.                                    |                |
|                                 | 33                    | HARTUNG H.P,TOYKA K.V.Activation of macrophages by substance P:induction of oxidative burst and thromboxane release.Eur J of Pharmacology.1983.Vol 89,pp. 301-305.                                                                                              |                |
| SA                              | 34                    | HEINERMAN J.Encyclopedia of healing juices.1994.Parker Publishing Co.New York.                                                                                                                                                                                  |                |
|                                 | 35                    | HOLZER P.Capsaicin:cellular targets,mechanisms of action, and selectivity for thin sensory neurons.Pharmacological Reviews.1991.Vol 43,pp. 143-201.                                                                                                             |                |
|                                 | 36                    | HOLZER P,SARIA A,SKOFITSCH G,LEMBECK F.Increase in tissue concentrations of histamine and 5-hydroxytryptamine following capsaicin treatment of newborn rats.Life Sciences.1981.Vol 29,pp. 1099-1105.                                                            |                |
|                                 | 37                    | HOLZER P,GAMSE R,LEMBECK F.Distribution of substance P in the gastrointestinal track:lack of effect of capsaicin pretreatment.Europ J of Pharmacology.1989.Vol 61,pp 303-307.                                                                                   |                |
|                                 | 38                    | ISSEKUTZ B,LIGHTNECKERT T,WINTER M.Effect of histamine,capsaicin and procaine on heat regulation.Archiv Inter de Pharmacodynamie et de Therapie.1950.Vol 83,pp.319-326.                                                                                         |                |

|                    |                   |                 |         |
|--------------------|-------------------|-----------------|---------|
| Examiner Signature | <i>A. Hoffman</i> | Date Considered | 4-25-07 |
|--------------------|-------------------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

|                                          |                               |                  |
|------------------------------------------|-------------------------------|------------------|
| <b>Sheet</b> <b>4</b> <b>of</b> <b>8</b> | <b>Application Number</b>     | 10/805,843       |
|                                          | <b>Filing Date</b>            | March 22, 2004   |
|                                          | <b>First Named Inventor</b>   | GONZALO ROMERO M |
|                                          | <b>Art Unit</b>               | 1654             |
|                                          | <b>Examiner Name</b>          |                  |
|                                          | <b>Attorney Docket Number</b> | ROMERO           |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|                    | 39                    | JANCSON, JANCSON-GABOR A, SZOLCSANYI J. Effect of capsaicin on thermoregulation. Acta Physiol Acad Scientiarum Hungaricae. 1966. Vol 29, p. 364.                                                                                                                |                |
|                    | 40                    | JANCSON-GABOR A, SZOLCSANYI J, JANCSON N. Irreversible impairment of thermoregulation induced by capsaicin and similar pungent substances in rats and guinea pigs. The Journal of Physiology. 1970. Vol 206, pp. 495-507.                                       |                |
| SH                 | 41                    | JOE B, LOKESH B. R. Role of capsaicin, curcumin and dietary n-3 fatty acids in lowering the generation of reactive oxygen species in rat peritoneal macrophages. Biochimica et Biophysica Acta. 1994. Vol 1224, pp. 255-263.                                    |                |
| SH                 | 42                    | JOHNSON A. R, ERDOS E. G. Release of histamine from mast cells by vasoactive peptides. Proceed of the Soc for Exper Biol and Med. 1973. Vol 142, pp. 1252-1256.                                                                                                 |                |
| SH                 | 43                    | KARRER T, BARTOSHUK L. Capsaicin desensitization and recovery on the human tongue. Physiology and Behavior. 1991. Vol 49, num 1, pp. 757-764.                                                                                                                   |                |
|                    | 44                    | KAUZMANN. Influence of temperature on biological system. Symposium of University of Connecticut. Editor Johnson F. H. American Physiol Soc. 1957.                                                                                                               |                |
|                    | 45                    | LIM LOMWONGSE L, CHAITAUCHAWONG C, TONGYAI S. Effect of capsaicin on gastric acid secretion and mucosal blood flow in rat. The J of Nutrition. 1979. Vol 109, pp. 773-777.                                                                                      |                |
| SH                 | 46                    | LJUNGDAHL A, KRISTENSSON K, LUNDBERG J. M, SVENNERHOLM B, ZIEGLER R. Herpes simplex virus in capsaicin treated mice. J of the Neurological Sciences. 1986. Vol 72, pp. 223-230.                                                                                 |                |

**Examiner  
Signature**

Stoffman

**Date  
Considered**

4-25-07

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number 10/805,843

Filing Date March 22, 2004

First Named Inventor GONZALO ROMERO M

Art Unit 1654

Examiner Name

Attorney Docket Number ROMERO

Sheet

5

of

8

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|                    | 47                    | LUNBLAD L, LUNBERG J.M, ANGGARD A, ZETTERSTROM O. Capsaicin-sensitive nerves and the cutaneous allergy reaction in man. Allergy. 1987. Vol 42, pp. 20-25.                                                                                                       |                |
|                    | 48                    | MAKARA G.B, GYORGY L, MOLNAR J. Circulatory and respiratory responses to capsaicin, 5-hydroxytryptamine and histamine in rats pretreated with capsaicin. Archives Internationales de Pharmacodynamie et de Therapie. 1967. Vol 170, pp. 39-45.                  |                |
|                    | 49                    | MATHEWS P.M, FROELICH G.J, SIBBITT W.L, BANKHURST A.D. Enhancement of natural cytotoxicity by B-endorphin. The J of Immunology. 1983. Vol 130, pp. 1658-1662.                                                                                                   |                |
| GA                 | 50                    | MCGILLS J.P, MITSUHASHI M, PAYAN D.G. Immuno-modulation by tachykinin neuropeptides. Annals of the N.J Acad of Sciences. 1990. Vol 594, pp. 85-93.                                                                                                              |                |
|                    | 51                    | MONSEREENUSORN Y. Subchronic toxicity studies of capsaicin and capsicum in rats. Chemical Pathology and Pharmacology. 1983. Vol 41, pp. 95-110.                                                                                                                 |                |
|                    | 52                    | MONSEREENUSORN Y, GLINSUKON T. The inhibitory effect of capsaicin on intestinal glucose absorption in vitro. Toxicology Letters. 1979. Vol 4, pp. 393-397.                                                                                                      |                |
| GA                 | 53                    | MONSEREENUSORN Y, KONGSAMUT S, PEZALLA P.D. Capsaicin-a literature survey. CRC Critical Reviews in Toxicology. 1982. Vol 10, pp. 321-339.                                                                                                                       |                |
|                    | 54                    | MONTAGNIER L. Virus. 2000. W.W. Norton and Co. N.J. London.                                                                                                                                                                                                     |                |
|                    | 55                    | MORTON C.R, CHAHL L.A. Pharmacology of the neurogenic oedema response to electrical stimulation of the saphenous nerve in the rat Arch of Pharmacology. 1980. Vol 314, pp. 271-276.                                                                             |                |

|                    |                 |                 |         |
|--------------------|-----------------|-----------------|---------|
| Examiner Signature | <i>Stoffman</i> | Date Considered | 4-25-07 |
|--------------------|-----------------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/805,843       |
| Filing Date            | March 22, 2004   |
| First Named Inventor   | GONZALO ROMERO M |
| Art Unit               | 1654             |
| Examiner Name          |                  |
| Attorney Docket Number | ROMERO           |

Sheet

6

of

8

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|                    | 56                    | <del>NAGY J.I, GOEDERT M, HUNT S.P, BOND A. The nature of the substance P-containing nerve fibres in taste papillae of the rat tongue. Neuroscience. 1982. Vol 7, pp. 3137-3151.</del>                                                                          |                |
|                    | 57                    | <del>NATIONAL INSTITUTE OF JUSTICE. CHRISTENSEN R.G, FRANK D.E. Preliminary Investigation of Oleoresin capsicum. NIH Report 100-95. 1995.</del>                                                                                                                 |                |
| SH                 | 58                    | NELSON E.K. Capsaicin, the pungent principle of capsicum, and the detection of capsicum. The J of Industrial and Engineering Chemistry. 1910. Vol 2, pp. 419-421.                                                                                               |                |
|                    | 59                    | <del>NELSON E.K. The constitution of capsaicin, the pungent principle of capsicum. II. The J of the American Chemical Society. 1920. Vol 41, pp. 597-599.</del>                                                                                                 |                |
|                    | 60                    | <del>NELSON E.K. The constitution of capsaicin, the pungent principle of capsicum. III. The J of the American Chemical Society. 1923. Vol 45, pp. 2179-2181.</del>                                                                                              |                |
| SH                 | 61                    | OLMSTED J.M.H. Prelude to calculus and linear algebra. 1968. Meredith Corp. New York.                                                                                                                                                                           |                |
|                    | 62                    | <del>PALECEK F, SANTAMBROGIO G, SANTAMBROGIO F, MATHEW O. Reflex responses to capsaicin: intravenous, aerosol and intratracheal administration. Journal of Applied Physiology. 1989. Vol 67, pp. 1428-1437.</del>                                               |                |
| SH                 | 63                    | PANERAI A.E, MARTINI A, LOCATELLI V, MANTEGAZZA P. Capsaicin decreases B-endorphin hypothalamic concentrations in the rat. Pharmacol Research Comm. 1983. Vol 15, pp. 825-832.                                                                                  |                |
| SH                 | 64                    | PAYAN D.G, BREWSTER D.R, MISSIRIAN-BASTIAN A, GOETZL E.J. Substance P recognition by a subset of human T lymphocytes. The J of Clinical Invest. 1984. Vol 74, pp. 1532-1539.                                                                                    |                |

|                    |                   |                 |         |
|--------------------|-------------------|-----------------|---------|
| Examiner Signature | <i>A. Hoffman</i> | Date Considered | 4-25-07 |
|--------------------|-------------------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|                                                                                                                                       |   |                          |                  |
|---------------------------------------------------------------------------------------------------------------------------------------|---|--------------------------|------------------|
| Substitute for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   | <b>Complete if Known</b> |                  |
|                                                                                                                                       |   | Application Number       | 10/805,843       |
|                                                                                                                                       |   | Filing Date              | March 22, 2004   |
|                                                                                                                                       |   | First Named Inventor     | GONZALO ROMERO M |
|                                                                                                                                       |   | Art Unit                 | 1654             |
|                                                                                                                                       |   | Examiner Name            |                  |
| Sheet                                                                                                                                 | 7 | of                       | 8                |
|                                                                                                                                       |   | Attorney Docket Number   | ROMERO           |

| NON PATENT LITERATURE DOCUMENTS |                       |                                                                                                                                                                                                                                                                 |                |
|---------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| SH                              | 65                    | PORSZASZ J, GYORGY L, PORSZASZ-GIBISZER K. Cardiovascular and respiratory effects of capsaicin. Acta Physiol Acad Scien Hungaricae. 1955. Vol 8, pp. 61-76.                                                                                                     |                |
|                                 | 66                    | <del>PORSZASZ J, SUCH GY, PORSZASZ-GIBISZER K. Circulatory and respiratory chemoreflexes. I. Acta Physiol Acad Scien Hungaricae. 1957. Vol 12, pp. 189-205.</del>                                                                                               |                |
|                                 | 67                    | <del>SCHERTEL E.R, ADAMS L, SCHNEIDER D.A, SMITH K.S, GREEN J.F. Rapid shallow breathing evoked by capsaicin from isolated pulmonary circulation. Journal of Applied Physiology. 1986. Vol 61, pp. 1237-1240.</del>                                             |                |
|                                 | 68                    | <del>SCHNEIDER M, DELUCA V, GRAY S. The effect of spice ingestion upon the stomach. The American J of Gastroenterology 1956. Vol 26, pp. 722-732.</del>                                                                                                         |                |
| SH                              | 69                    | SHAKHASHIRI. Chemical of the Week, ethanol. Chemical Industry. Internet                                                                                                                                                                                         |                |
| SH                              | 70                    | SIMONE D.A, BAUMANN T.K, LA MOTTE R.H. Dose-dependent pain and mechanical hyperalgesia in humans after intradermal injection of capsaicin. Pain. 1989. Vol 38, pp. 99-107.                                                                                      |                |
|                                 | 71                    | <del>SKOPITSOH G, BONNERER J, PETRONIJEVIC S, SARIA A, LEMBECK F. Release of histamine by neuropeptides from the perfused rat hindquarter. Archiv of Pharmacol. 1983. Vol 322, pp. 153-157.</del>                                                               |                |
| SH                              | 72                    | STASCH A.R, JOHNSON M.N. Antioxidant properties of chile pepper. J of American Dietetic Association. 1970. Vol 56, pp. 409-412.                                                                                                                                 |                |
|                                 | 73                    | <del>SURHY J.J, LEE S.S. Capsaicin, a double-edged sword: toxicity, metabolism, and chemopreventive potential. Life Sciences. 1995. Vol 56, pp. 1845-1855.</del>                                                                                                |                |

|                    |                 |                 |         |
|--------------------|-----------------|-----------------|---------|
| Examiner Signature | <i>Stoffman</i> | Date Considered | 4-25-07 |
|--------------------|-----------------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/805,843       |
| Filing Date            | March 22, 2004   |
| First Named Inventor   | GONZALO ROMERO M |
| Art Unit               | 1654             |
| Examiner Name          |                  |
| Attorney Docket Number | ROMERO           |

Sheet

8

of

8

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|                    | 74                    | <del>SZOLCSANYI J, JANCISO GABOR A. Sensory effects of capsaicin congeners-I. Relationship between chemical structure and pain-producing potency of pungent agents. Arzneimittel Forschung Drug Research. 1975. Vol 25, pp. 993-1094.</del>                     |                |
| SH                 | 75                    | TIMMERSON C. A few simple techniques for staying alive. Home remedies for the A.I.D.S. Holocaust. Journal of Orthomolecular Medicine. 1990. Vol 5, pp. 25-31.                                                                                                   |                |
|                    | 76                    | <del>VIRANUVATTI V, KALAYASIRI C, CHEARANI O. Effect of capsicum solution on human gastric mucosa as observed gastroscopically. 1972. Vol 58, pp. 225-232.</del>                                                                                                |                |
| SH                 | 77                    | VISUDHIPHAN S, POOLSUPPASIT S, PIBOONNUKARINTR O, TUMLIANG S. The relationship between high fibrinolytic activity and                                                                                                                                           |                |
| SH                 |                       | daily capsicum ingestion in thais. The American J of Clinical Nutrition. 1982. Vol 35, num 1, pp. 1452-1458.                                                                                                                                                    |                |
|                    | 78                    | <del>ZINSSER H. Microbiology. 1972. Prentice-Hall.</del>                                                                                                                                                                                                        |                |
| SH                 | 79                    | ZHANG Z, HAMILTON S.M, STEWART C, STROTHER A, TEEL R.W. Inhibition of liver microsomal cytochrome P450 activity and metabolism                                                                                                                                  |                |
| SH                 |                       | of the tobacco-specific nitrosamine NNK by capsaicin and ellagic acid. Anticancer Research. 1993. Vol 13, pp. 2341-2346.                                                                                                                                        |                |
|                    |                       |                                                                                                                                                                                                                                                                 |                |

Examiner  
Signature

Stoffman

Date  
Considered

4-25-07

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.